REMARKS

This communication is in response to the outstanding Official Action dated July 12, 2001. The shortened statutory period for filing a response is set to expire October 12, 2001. In view of these amendments and remarks, reconsideration of the Examiner's rejection is requested and a Notice of Allowance of all pending claims is respectfully requested. Additionally, Applicant is requesting a phone interview with the Examiner to facilitate allowance of the application. Entry of the amendment and reconsideration pursuant to 37 C.F.R. §§ 1.112 and 1.116 are appropriate as the amendment corrects minor typographical errors noted by the Examiner in the final rejection and do not require a new search. Further, the response addresses what Applicant respectfully submits is a misconception. Therefore, at the very least, this amendment will reduce and/or clarify issues on appeal.

Initially, Applicant notes that claims 19 and 20 have been amended to address the objection because bee venom was misspelled.

Claims 11, 22 and 26 were again rejected pursuant to 35 U.S.C. § 102(b) as allegedly being anticipated by *Steigerwaldt et al.* The Examiner's comments contained in paragraph six of the above-identified Official Action emphasize the simultaneous or consecutive nature of administering anesthetic and bee venom for rheumatoid arthritis. Applicant believes that this is illustrated by the Examiner's use of Bold Typeface for the phrase **"simultaneously or consecutively"**. Applicant believes, however, that that is not the issue. First, Applicant notes that absolutely nothing in *Steigerwaldt* discusses the timing or order of administration of bee venom and topical anesthetic. Absent some specific citation from the reference itself to support the Examiner's position, the Patent Office has failed to establish a *prima facie* case of anticipation.

But even if the Patent Office were correct in this regard, Applicant maintains that the claimed invention is not anticipated. Under its most generous interpretation, *Steigerwaldt* teaches intradermal injection of bee venom. But *Steigerwaldt* suggests nothing about the mode of administration of the anesthetic. Nothing in the Examiner's comments addresses this point. Since *Steigerwaldt* does not explicitly teach simultaneous or consecutive administration or anything regarding the mode of administration of the anesthetic, it cannot anticipate the claimed invention. Indeed, looking at the body of the entire article, the only discussions of injection are in the context of bee venom. It is impossible to tell anything about how the "procaine hydrochloride 0.2%" is administered and when it is administered.

Claims 11, 22, 26 and 27 were again rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over *Steigerwaldt et al.* in view of *Ogram et al.* because the Examiner believes that *Steigerwaldt* teaches the use of bee venom and local anesthetic, procaine, for therapeutic use including rheumatoid arthritis and that the only difference between *Steigerwaldt* and the claimed invention is that *Steigerwaldt* teaches the use of procaine as the local anesthetic rather than lidocaine. *Ogram et al.* is thus cited as teaching the use of a specific local anesthetic or lidocaine to reduce pain resulting from bee stings.

But *Steigerwaldt et al.* does not teach the injection of both bee venom and the local anesthetic. Indeed, *Ogram et al.* does not teach the injection of either bee venom or anesthetic. And neither *Steigerwaldt* nor *Ogram* specifically teach simultaneous or consecutive administration of a local anesthetic and bee venom.

Indeed, *Ogram* does not teach "administration" of a bee venom at all. It discusses a way of dealing with bee stings. Why would a person of ordinary skill in the art seek to combine

the controlled therapeutic application of bee venom as medicine with techniques which involve warding against or counteracting the effects of uncontrolled bee attacks? Moreover, if anything, *Ogram et al.* supports Applicant's reading of *Steigerwaldt et al.* in as much as it suggests that the art recognizes means of administering a local anesthetic in this context is topically, not by injection.

Additionally, the Examiner indicated that a declaration may be appropriate for arguments contained within Applicant's previous response. While the Applicant may consider submitting such a declaration, the Applicant notes that the statements found in the previous Amendment are fully supported in the specification as filed. (See specification at pages 4 and 5).

In view of the above remarks, the Patent Office has failed to establish a *prima facie* case of anticipation or obviousness based upon the applied references. Applicant respectfully submits that all claims presently set forth in this application possess the requisite novelty, utility and nonobviousness to warrant their immediate allowance, which action is respectfully solicited. Finally, the Applicant again request the opportunity of an interview with the Examiner at the time when the Examiner is reconsidering the case.

As it is believed that all of the rejections set forth in the Official Action has been fully met, favorable reconsideration and allowance are earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he telephone applicant's attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Respectfully submitted,

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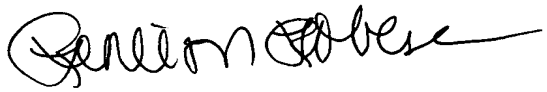

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MARKED-UP COPY OF AMENDED CLAIMS:

19. The method of claim 15 wherein said bee venom is administered in an amount of between about 0.01 mg and about 1.0 mg per injection.

20. The method of claim 19 wherein said bee venom is administered in an amount of between about 0.05 mg and about 0.5 mg per injection.